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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,963	12/27/2001	Mark D. Velligan	033052-007	7363

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/10/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/026,963

Applicant(s)

VELLIGAN ET AL.

Examiner

Sonya Wright

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) 1-15, 20 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-22 are pending in this application.

#### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-16 and the species of compound 177 in Figure 10, also found in Example 36, and in Claim 21 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Group I and claims 20 and 21 of Group III should be combined. This has been found persuasive and claims 20 and 21 of Group III have been rejoined with Group I.

The following generic concept as depicted in claim 1 is identified for examination along with the elected embodiment:  $R^1$  and  $R^2$  are independently of each other  $-COR^3$  wherein  $R^3$  is selected from the group consisting of alkyl, amino, or alkyl substituted with one, two or three substituents selected from the group consisting of amino, guanidine, amidino, aminoacyl,  $-NHCOR^a$  (wherein  $R^a$  is hydrogen, alkyl, substituted alkyl, aryl, aralkyl, cycloalkyl, cycloalkylalkyl),  $-NHCONHR^a$  (wherein  $R^a$  is as defined above), aryl, carboxy, alkoxycarbonyl, and  $OR^b$  (where  $R^b$  is hydrogen, alkyl, aryl, aralkyl, cycloalkyl, or cycloalkylalkyl) provided that at least one of  $R^1$  and  $R^2$  is a group which can form a pharmaceutically acceptable acid addition salt;  $n$  and  $m$  are 0;  $Ar^1$  is pyrrolyl,  $Ar^4$  is pyrrolyl; and  $L$  is ethyl.

The remaining subject matter of claims 1-16, 20, and 21 in part and claims 17-19 and 22 in their entirety stands withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

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The withdrawn subject matter of claims 1-16 in part and claims 17-19 and 22 in their entirety is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

Claims 1-16, 20 and 21 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified supra.

The requirement is still deemed proper and is therefore made FINAL.

#### **DETAILED ACTION**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.

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- 4) Level of predictability in the art
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 15 is directed to "a method for the treatment of diseases caused by pathogenic organisms". The specification does not reasonably provide enablement for the instantly claimed method of use.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. Prior arts do not indicate which "diseases caused by pathogenic organisms" may be treated by the claimed compound. There is little predictability in the art of which modifications may be made to the claimed compound which would retain its ability to be useful in treating diseases caused by pathogenic organisms. The term "pathogenic organisms" may encompass a vast amount of subject matter, and there are a vast number of diseases caused by pathogenic organisms. Without some guidance as to what changes may be made to the compounds of formula I, there would be little predictability in using the claimed compounds in treating diseases caused by pathogenic organisms. The level of ordinary skill in the art is high. The specification provides limited working examples and limited guidance. Pathogenic organisms are broadly defined in the specification as viruses, bacteria, parasites, and fungi; and viruses, bacteria, parasites, and fungi themselves embrace a plethora of subject matter.

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The skilled artisan would have a numerous amount of modifications to perform in order to use the compound claimed in treating diseases caused by pathogenic organisms.

This rejection can be overcome by limiting claim 15 to the diseases caused by pathogenic organisms, which are supported in the specification.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is drawn to "a method for the treatment of diseases caused by pathogenic organisms". It appears that Applicant intends for claim 16 to be further limiting of claim 15 by reciting in claim 16 that "the disease is cancer". However, in the specification, on page 1, lines 16-19, and on page 2, lines 23-26, "cancer" is not listed as a disease caused by a pathogenic organism. Appropriate correction is required.

### **ABSTRACT**

The abstract of the disclosure is objected to because: in line 10, the word "compound" should be replaced with —compounds— and a period should be inserted at the end of the abstract. Correction is required. See MPEP § 608.01(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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\_\_\_\_\_  
Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

February 4, 2003